AFFIDAVIT IN SUPPORT OF CRIMINAL COMPLAINT

- 1. I, Kristina Ruisanchez, am a Special Agent (SA) with the United States Food and Drug Administration (FDA), Office of Criminal Investigations (OCI), currently assigned to the San Juan Resident Office. I have been so employed since October of 2016. I was also a SA with the United States Secret Service from May of 2009 through October 2016. I possess a Bachelor of Science from the University of Puerto Rico. I am also a graduate of the Federal Law Enforcement Training Center and the U.S. Secret Service Academy.
- 2. As a result of my personal participation in this investigation as co-case agent, I am familiar with the circumstances described in this affidavit. I have either personally interviewed those whose information is set forth herein, or reviewed reports of interviews or other investigative information prepared by those persons. However, since this affidavit is being submitted for the limited purpose of establishing probable cause pertaining to certain violations of law, it does not include all the facts that have been learned during the course of the investigation. When the content of documents or statements of others are reported herein, they are reported in substance and part unless otherwise indicated. Instead, I have set forth only the facts I believe are necessary to evaluate the legal basis for a criminal complaint. This affidavit is submitted in support of a criminal complaint detailing probable cause to believe that JUAN CARLOS PEREZ CAMACHO (hereinafter PEREZ-CAMACHO) is in violation of Title 18, United States Code, Sections 1001 [False statements]; 1546 [Fraud and misuse of visa, permits, and other documents]; and Title 21, United States Code, Section 331(k), 352(f)(1), 353(b)(1), and 333(a)(1) and (2)[Misbranded Drugs and Devices].

BACKGROUND

- 3. The United States Customs and Border Protection (CBP) is the border enforcement agency for the United States, and it accomplishes this mandate in part by controlling, regulating, and facilitating the movement of carriers, people, and commodities between the United States and other nations.
- 4. The United States Citizenship and Immigration Services (USCIS) is an agency of the United States Department of Homeland Security that administers the country's naturalization and immigration system.
- 5. Homeland Security Investigations (ICE-HSI) is the investigative arm of the U.S. Department of Homeland Security that enforced over 400 statutes related to U.S. Customs and Immigration Law, to include but not limited to Money Laundering, Bulk Cash Smuggling and Documents and Benefits Fraud.
- 6. The U.S. Department of State Bureau of Diplomatic Security Services (DSS) is the law enforcement branch tasked with securing diplomacy and protecting the integrity of U.S. travel documents.
- 7. The U.S. Food and Drug Administration (FDA) is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"). FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce. One of the purposes of the FDCA is to ensure that drugs and medical devices sold for human use are safe and effective, and bear labeling containing only true and accurate information.

- 8. The FDCA defines a medical "device" as, among other things, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in a man or other animals, or intended to affect the structure or function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not depended upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. §§321(h)(2), 321(h)(3).
- 9. A "prescription device" is a device which, because of its potential for harmful effects, methods of use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to direct the use of such device. 21 C.F.R. § 801.109.
- 10. Under the FDCA, devices are deemed to be "misbranded" unless their labeling bears adequate directions for use. 21 U.S.C. § 352(f)(1). Under regulations promulgated by the FDA, "adequate directions for use" is defined as directions under which a layman can safely use a drug or device for its intended uses. 21 C.F.R. § 801.5.
- 11. Prescription devices by their very nature are safe for use only under the supervision of a licensed practitioner. See 21 C.F.R. § 801.109. Adequate directions for use, therefore, cannot be written for prescription devices, and prescription devices are per se misbranded under 21 U.S.C. § 352(f)(1). To allow for the lawful movement of prescription devices in interstate commerce, FDA regulations exempt prescription devices from the adequate directions for use

requirement, but only if certain conditions are met. See 21 C.F.R. §§ 201.100 (drugs) and 801.109 (devices).

- 12. Two such conditions require that the device is: (a) in the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; and (b) is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice. See 21 C.F.R. § 801.109(a)(1)(i) and (2).
- 13. The FDCA defines a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," and "articles (other than food) intended to affect the structure or any function of the body of man," and "articles intended for use as a component of" the foregoing. 21 U.S.C. § 321(g)(1)(B), (C) and (D).
- 14. "Prescription drugs" are drugs that, because of their toxicity and other potential for harmful effects, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(l)(A). A drug is also a prescription drug if the FDA requires it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA's approval of the drug. 21 U.S.C. § 353(b)(l)(B).
- 15. Prescription drugs can lawfully be dispensed only upon the valid prescription of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1). Under the FDCA, the act of dispensing a prescription drug without a valid prescription is deemed to be an act that resulted in the drug being misbranded while held for sale.
- 16. The FDCA prohibits the doing, or causing thereof, of any act to a device or a drug, after the device and/or drug and/or their components have traveled in interstate commerce and while held for sale, that results in the drug and/or device being adulterated or misbranded. 21 U.S.C.

- § 331(k). Any person who commits a prohibited act under the FDCA commits a misdemeanor crime, regardless of any mens rea, punishable by a maximum of imprisonment for one year and a \$100,000 fine. 21 U.S.C. § 333(a)(1) and 18 U.S.C. § 3571. If committed with the intent to defraud or mislead, the violation constitutes a felony crime and is punishable by up to three years imprisonment and a \$250,000 fine. 21 U.S.C. § 333(a)(2) and 18 U.S.C. § 3571.
- 17. Based on my training and experience, and in conversations with other investigators, I know that dental prosthetic devices are regulated by the FDA, are limited to prescription use only, and are used by the cosmetic dentist to restore a single tooth or in most instances multiple teeth on the upper arch to create a big bright "Hollywood" type of smile makeover. Porcelain powder for clinical use in dentistry, including in the production of veneers, is a Class II medical device under the FDCA. 21 C.F.R. § 872.6660.
- 18. Based on my training and experience, and in conversations with other investigators, I know that xylocaine is an injected local-anesthetic drug typically used in dentistry, and it is a "prescription drug" under the FDCA.
- 19. The Puerto Rico Board of Dental Examiners is the entity responsible for administering the requirements for admission to, and licensing individuals for, the practice of dentistry in the Commonwealth of Puerto Rico.
- 20. On September 3, 2004, the Puerto Rico Pharmacy Board adopted law 247 titled as the "Law of Pharmacy". Chapter 1, Article 1.03 paragraph (ww) of this regulation provides that a valid prescription is "an original written order issued and signed by a medical facultative such as a physician, dental surgeon, dentist, podiatrist or whenever the usage is for animals, a veterinarian doctor, in the normal course and lawful exercise of their profession in Puerto Rico." Chapter 1, Article 1.03 paragraph (ss) of this regulation further defines who can be a prescriber

as "a physician, doctor, dental surgeon, dentist, podiatrist or veterinary doctor authorized to practice in Puerto Rico, who issues a prescription for dispensing medication with whom a valid professional relationship is held."

FACTS ESTABLISHING PROBABLE CAUSE

- 21. This is an investigation being conducted by ICE-HSI, the DSS, and FDA Office of Criminal Investigations (FDA-OCI), into the illegal administration of medications and provision of cosmetic dental services by an unlicensed individual to multiple patients. The investigation has revealed that cosmetic dentistry services provided by PEREZ-CAMACHO are being unlawfully rendered as an unlicensed and/or unauthorized individual.
- 22. PEREZ-CAMACHO is national of Colombia, who has been illegally practicing dentistry in Puerto Rico since approximately 2018. It was corroborated with the Puerto Rico Board of Dental Examiners that PEREZ-CAMACHO does not have, nor has he ever held, a license to practice dentistry in Puerto Rico.
- 23. CBP border crossing records reflect PEREZ-CAMACHO has been continuously entering and exiting the United States as a B1/B2 Visa holder since as early as 2015, when the B1/B2 Visa was originally issued.
- 24. A B1/B2 Visa is for nonimmigrant visitors who want to enter the United States temporarily for business (visa category B-1), for tourism (visa category B-2), or for a combination of both purposes (B-1/B-2).
- 25. Activities permitted as a Business B1 Visa holder include but are not limited to: the consultation with business associates; attend scientific, educational, professional or business conventions or conferences; settle an estate; and negotiating a contract.

- 26. Activities permitted as a Tourism B2 Visa holder include but are not limited to: tourism; vacation (holiday); visit with friend or relatives; receive medical treatment; participate in social events hosted by a fraternal, social or service organizations; participating in amateur musicals, sports and similar events or contests not being paid for participating; and enrollment in a short recreational course of study, not for credit toward a degree (for example, a two-day cooking class while on vacation).
- 27. As a B1/B2 Visa holder PEREZ-CAMACHO was specifically prohibited from being involved in any employment activity or receive payment for it.
- 28. In February of 2018, PEREZ-CAMACHO was scheduled to return to Colombia on the same day as two female Colombian nationals subsequently found in possession of approximately \$17,977 dollars in U.S. currency during an outbound inspection by CBP Officers at the Miami airport. During the incident the two female Colombian nationals identified themselves as the dental assistants for PEREZ-CAMACHO.
- 29. CBP records reflect that PEREZ-CAMACHO is in a common law marriage relationship with Mrs. Carmen Lucia Gomez-Libreros (hereinafter Gomez-Libreros) a Colombian national and a holder of a B1/B2 Visa in the United States.
- 30. USCIS records show that between on or about May and June, 2019 PEREZ-CAMACHO filed an I-485 Form (Application for Lawful Permanent Resident Status in the United States). As a result, a Work Authorization was granted by USCIS effective for the period of May 8, 2019 to May 7, 2020. Work authorization granted would allow PEREZ-CAMACHO to be perform a lawful work.

- 31. On July 11, 2018, Mrs. Naishary Ramirez-Garcia, a 25 year old, U.S. citizen and resident of Villa Palmeras in San Juan, PR, filed an I-130 (Petition for Alien Relative) claiming that Ramirez-Garcia was PEREZ-CAMACHO's wife.
- 32. USCIS thereafter reviewed the I-130 application, and on May 23, 2019, interviewed PEREZ-CAMACHO to review the legitimacy of the content of the application; USCIS subsequently referred the application to the USCIS Fraud Detection and National Security Division for further investigation.
- 33. During the interview, PEREZ-CAMACHO stated and completed a record of Sworn Statement where he was asked and declared the following:
 - a. Have you ever worked in the United States without authorization? PEREZ-CAMACHO stated, "No."
 - b. Have you ever lied to any U.S. Government Official to gain entry or admission into the United States or to gain immigration benefits while in the United States? PEREZ-CAMACHO testified, "No."
 - c. Have you ever violated the terms or conditions of your non-immigrant status?

 PEREZ-CAMACHO stated, "No."
- 34. During the same May 23rd, 2019 interview, PEREZ-CAMACHO indicated under oath to USCIS that he has never been gainfully employed in the United States while being a B1/B2 visa holder.
- 35. On October 1, 2019, patient "AMA" (use of initials to protect victim identity) was interviewed by ICE-HSI Special Agents (SA) Wallace A. Bustelo and Gerardo Mujica; DSS SA Walter A. Rios and Task Force Officer Emily Roman; and FDA-OCI SA Kristina Ruisanchez at the FDA-OCI office in San Juan, PR who wanted to report the illegal cosmetic dentistry practice

activities regarding PEREZ-CAMACHO. Accompanying AMA were Puerto Rico Police Department (PRPD) Agents Lourdes Pagan (Badge #28117) and I. Ortiz (Badge #36632) from the Carolina Sexual Crimes Unit whom AMA had originally contacted to present a complaint against PEREZ-CAMACHO.

- 36. AMA originally met PRPD agents to file a sexual assault compliant against PEREZ-CAMACHO. According to AMA, on September 25, 2019, PEREZ-CAMACHO sexually assaulted her after the completion of a dental procedure performed by PEREZ-CAMACHO inside apartment #304 of the Marbella West Tower (later identified by agents as Marbella Del Caribe condominium complex) located in #5347 Isla Verde Avenue, Carolina, PR 00979.
- 37. The dental procedure performed by PEREZ-CAMACHO on AMA on September 25, 2019, consisted of a follow-up dental clean-up visit after a previous cosmetic dental procedure performed on or about July of 2018, at apartment #208 of the Marbella East Tower (Marbella Del Caribe condominium complex), located in #5349 Isla Verde Avenue, Carolina, PR 00979. The July 2018, dental cosmetic procedure performed by PEREZ-CAMACHO on AMA consisted of an aesthetic procedure that included the injection of anesthesia in both sides of the upper gum and the opening of the gums to insert or attach on each tooth a device or devices to improve the appearance of the same, similar to dental veneers.
- 38. During said procedure AMA paid PEREZ-CAMACHO \$2,800.00 in cash for the cosmetic medical procedure. AMA provided the agents with photos taken while the procedure was being performed. In one of the photos PEREZ-CAMACHO is partially visible and wearing blue medical uniform bearing the partial name of "Juan C..." and the partial title of "Ortodoncia y..." while performing the cosmetic dental procedure on AMA. During the September 25, 2019, follow-up clean-up procedure, AMA paid \$140.00 in cash.

- 39. AMA indicated having first heard about PEREZ-CAMACHO and the cosmetic dental services PEREZ-CAMACHO provided in Puerto Rico (PR) through a former co-worker named "TZ Last Name Unknown (LNU)," who also had the same cosmetic dental procedure performed on her by PEREZ-CAMACHO at the Cond. Marbella del Caribe Apartment #208 location and had paid \$2,800.00. In or about, June 2018, AMA was present while PEREZ-CAMACHO performed the dental procedure on "TZ LNU" and AMA specifically saw PEREZ-CAMACHO inject/administer anesthesia with a large syringe and getting the cosmetic dental devices installed on "TZ LNU." AMA further indicated that he/she also saw "TZ LNU" pay PEREZ-CAMACHO \$2,800.00 in cash. Other former co-workers of AMA that had the same cosmetic dental procedure performed by PEREZ-CAMACHO included "T LNU" and "N LNU."
- 40. AMA stated that both residential apartments where the dental procedures where performed had no markings identifying them as a dental clinic or medical office. Once inside, AMA was able to observe in the living room a flat medical table where the dental/medical procedures were performed. AMA also observed dental equipment commonly found in dental clinics. AMA stated that he/she assumed PEREZ-CAMACHO was not licensed to perform dental procedures in the United States because PEREZ-CAMACHO told AMA during the last visit that he only accepted clients by referral and did not want publicity until he established a formal office. Hence, the reason he only accepted cash as a method of payment. AMA stated that PEREZ-CAMACHO worked by himself and he/she never saw any dental assistant or employees with PEREZ-CAMACHO.
- 41. AMA indicated that the method of contacting PEREZ-CAMACHO was via the WhatsApp application under telephone number +57 300 6509 277 and display name of "Dr Juankaperez." AMA provided a copy of the chats with PEREZ-CAMACHO. A review of the

communications between AMA and PEREZ-CAMACHO, revealed that on June 28, 2018 AMA originally established contact mentioning "TZ LNU" as the friend who referred AMA to obtain PEREZ-CAMACHO's dentistry services.

- 42. Further review of the WhatsApp application communication between AMA and PEREZ-CAMACHO, revealed the following:
 - a. On June 29, 2018, PEREZ-CAMACHO confirmed that he would charge AMA \$2,800.00 dollars in U.S. currency, which is the same amount he billed "TZ LNU." On the same date, PEREZ-CAMACHO scheduled the dental procedure to take place on July 6, 2018, at 8:00a.m.
 - b. On July 5, 2018, AMA confirmed the appointment was still in place for the next day and PEREZ-CAMACHO provided further pre-procedure instructions.
 - c. On July 6, 2018, at approximately 7:31 a.m. AMA arrived near Cond. Marbella location at the Isla Verde Avenue in Carolina, PR. PEREZ-CAMACHO told AMA that the address was "Torre Este Apto. 208" and instructed AMA to come up stairs.
 - d. On July 6, 2018, at approximately 1:56 p.m. PEREZ-CAMACHO sent via WhatsApp approximately twenty-three (23) images of the before and after of the cosmetic dental treatment that were taken by PEREZ-CAMACHO.
 - e. On October 11, 2018, at approximately 8:26 a.m. AMA asked PEREZ-CAMACHO via WhatsApp as to the follow-up treatment and PEREZ-CAMACHO indicated it is done every six (6) months.
 - f. After several attempts from AMA to confirm that PEREZ-CAMACHO was available for the follow-up maintenance procedure, on September 24, 2019, PEREZ-CAMACHO responded via WhatsApp and confirmed that he was in PR and scheduled

the maintenance appointment for AMA to take place on September 25, 2019, at 3:00 p.m., indicated that it would have a cost of \$140.00 in cash and that he was still operating out of the same building complex, however, at the "Torre Oeste, in front of pizza city."

- g. On September 25, 2019, at approximately 2:47 p.m., AMA confirmed via WhatsApp that he/she arrived at the location and PEREZ-CAMACHO instructed AMA to tell the security guard that he/she was coming as a visitor to apartment 304 ("Dices que vas de visita al 304 y ya llamo al guardia").
- 43. A social media accounts verification revealed that a significant number of well-known celebrities and tv personalities have received dentistry services by PEREZ-CAMACHO and have been documented in numerous pictures that PEREZ-CAMACHO has posted within Facebook ("Dr. Juan Carlos Pérez") and Instagram ("dr.juankperez" and "juankperez.dr") accounts.
- 44. On October 4, 2019, at approximately 1:20p.m. HSI SA Bustelo and Mujica accompanied by DSS SA Rios conducted a site check at Cond. Marbella del Caribe Oeste, apartment 304, #5347 Isla Verde Avenue in Carolina, PR 00979 and upon approaching the apartment 304 door they were able to hear outside in the hallway what, based on our experience were able to identify as the operation of a dentistry drill behind the door of apartment 304.
- 45. On the same date, at approximately 3:30pm, agents returned to the location and once again listened to the same sound of what appeared to be a dentistry drill coming from behind the door of apartment 304, very noticeable from the hallway.
- 46. On October 08, 2019, a U.S. Magistrate Judge in the District of Puerto Rico authorized a search warrant for the residence that was identified as the dentistry office of PEREZ-CAMACHO, Cond. Marbella del Caribe Oeste, apartment 304, #5347 Isla Verde Avenue in Carolina, PR 00979.

- 47. On October 09, 2019, agents learned that PEREZ-CAMACHO departed Puerto Rico to New York on October 07, 2019 and was scheduled to return to Puerto Rico on October 15, 2019.
- 48. On October 15, 2019, PEREZ-CAMACHO was observed arriving in Puerto Rico via United Airlines flight # 1523 from Newark. PEREZ-CAMACHO was seen by agents carrying a black backpack and recover a large blue in color luggage from baggage claim and travel to Ramirez-Garcia's residence in Villa Palmeras. At the residence, PEREZ-CAMACHO was observed by agents putting the black backpack and the large blue in color luggage in another vehicle and drive to Marbella del Caribe Oeste Condominium. PEREZ-CAMACHO was later observed entering apartment 304 while carrying the black backpack and the large blue in color luggage.
- 49. On the same date, federal agents executed previously issued search warrant at Cond.

 Marbella del Caribe Oeste, apartment 304, #5347 Isla Verde Avenue in Carolina, PR 00979, and the following items were found:
 - a. PEREZ-CAMACHO's passport, which was found to contain CBP Entry Stamps to multiple ports of entry in the United States. A review of the CBP Entry Stamps revealed that PEREZ-CAMACHO entered the United States through the following ports of entry and in the following dates:
 - Miami, FL dated February 25, 2016, May 07, 2016, and October 09, 2016;
 - San Juan, PR dated July 27, 2016; November 27, 2016, June 28,
 2017, and February 09, 2018;
 - New York dated February 22, 2017 and November 28, 2017.
 - b. Bottles of Xylocaine (injectable anesthetic for Rx use only).

- c. UPS shipping bag bearing tracking # 1Z F93 9Y0 04 5292 9358. The shipping label revealed the shipper was Gomez-Libreros, CLL6A 80 160 apto 112 760002 Cali Colombia. The intended recipient was Carlos Delgado, Higuerillo Fajardo P.R. 00738 Urb. Fajardo Gardens 486, Fajardo, PR 00738. The shipping bag contained multiple packages of Empress Direct Filling Material labeled in part imported by Representaciones Eurodent S.A.S., Av. Calle 127 N 7-70 Bogota, Colombia and IPS Empress Direct-Vivadent. The shipping label was stamped with the date February 28, 2018.
- d. DHL Shipping box bearing the following information on the shipping label: Airway Bill number 31 5471 6596, the shipper appeared to be Silvia Olga Camacho, with address CRA 80 #5 120 apto 108, Cali 760001 Colombia. The intended recipient was Luz Nelly Garcia, with address Calle Karla Michelle D13B, Villa Palmeras, San Juan PR 00915. The contents were described as Dental Samples.
- e. Premium Multi Layer Acrylic teeth, labeled in part Starvit. Starvit was later identified as a Colombian company located in Carrera 42 #39 Sur 90 Medellin-Colombia.
- f. Dentistry tools and materials such as: ART Electron Electrosurgery, periodontal Dental Resin, Valo Cordless Curing Light Graphite, drill, suction, massage table, syringes, tartar scraper, mouth mirror, periodontal probe, periodontal scaler, waxing instruments, among others.
- g. Multiple receipts of Western Union dated September 21, 2019, for \$1,000.00 each. The information contained in the receipts are detailed as follows:
 - i. One transaction conducted at Coco Supermarket, 1965 Ave. Borinquen,
 Bo. Obrero, PR sent to Claudia Camacho Hoyos in Colombia.

- ii. One transaction conducted at Coco Supermarket, 1965 Ave. Borinquen,Bo. Obrero, PR sent to Daniel Felipe Nunez Camacho in Colombia.
- iii. One transaction conducted at Plaza Loiza #10 Norte, Ave. Baldorioti de Castro, SR 26 Esq Betances, PR, sent to Mauricio Giraldo Jimenez in Colombia.
- h. Receipts of deposit dated October 08, 2019 in a Bank of America account ending in xx3481, deposited in New York according to the address on the receipt, in the amount of \$4,800.00.
- 50. In the large blue in color luggage, agents found dentistry tools, other medical equipment and bulk cash. In total, approximately \$10,784.00 was found in the apartment.
- 51. During the execution of the search warrant, PEREZ-CAMACHO, was found in possession of two (2) cell phones. PEREZ-CAMACHO stated to FDA-OCI SA Ruisanchez that one cellphone was from Puerto Rico and the other was from Colombia.
- 52. A review of the cellphone contents revealed multiple videos and photographs of patients receiving dentistry services by PEREZ-CAMACHO. Several videos show PEREZ-CAMACHO receiving money in cash for his dentistry services.
- 53. An analysis of the videos and photographs revealed that multiple videos and photographs were taken during dates that PEREZ-CAMACHO was in the United States.
- 54. Based on the above information, I allege there is probable cause to believe JUAN CARLOS PEREZ CAMACHO has committed a violation of Federal law, to wit: Title 18, United States Code, Sections 1001 [False statements]; 1546 [Fraud and misuse of visa, permits, and other documents]; and Title 21, United States Code, Section 331(k), 352(f)(1), 353(b)(1), and 333 (a)(1) and (2)[Misbranding Drugs and Devices].

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I hereby declare that the above affidavit is true and correct to the best of my knowledge pursuant to the investigation conducted in this case.

Special Agent Kristina Ruisanchez

U.S. Food and Drug Administration

Office of Criminal Investigations

Subscribed and sworn before me on the 16th day of October, 2019.

United States Magistrate Judge

District of Puerto Rico